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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,682	10/04/2000	Gilles H. Tapolsky	359872000810	3633
7590	12/12/2005		EXAMINER	
A James Nelson Esq Schwegman Lundberg Woessner & Kluth 1600 TCF Tower 121 South Eighth Street Minneapolis, MN 55402			GRAFFEO, MICHEL	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 12/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/684,682	Applicant(s) TAPOLSKY ET AL.	
	Examiner Michel Graffeo	Art Unit 1614	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22, 24 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 24 and 34-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>18 Jul 05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

Claims 19-22, 24 and 34-42 are pending and examined.

As Applicant has pointed out in the Response filed 18 October 2004, claims 34, 36-39, 41 and 42 have not been withdrawn from consideration. Additionally, Applicant notes on page 5 of the Response (Remarks section) that claim 19 has been amended but no such amendment is noted in this, most recent, Response.

In light of the new grounds for rejection, the previous rejection under 35 U.S.C. 103(a) is withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22, 24 and 34-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the

claim and determined that the invention would work for its intended purpose or an applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. Claim 1 recites the limitation "free of a plasticizer" relative to the first adhesive layer. Claims are read in light of the Specification and although the terms of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. In re Cohn, 438 F.2d 989, 169 USPQ 95 (CCPA 1971); In re Hammack, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). Noting that no claim may be read apart from and independent of the supporting disclosure on which it is based, the language on page 14:

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As described above, the erosion kinetics of one or more of the layers (adhesive layer, backing layer, or both) may be altered in many different ways in order to modify the residence time and the release profile of a drug. One way is by crosslinking or plasticizing the film-forming polymer. Crosslinking agents known in the art are appropriate for use in the invention and may include glyoxal, propylene glycol, glycerol, dihydroxy-polyethylene glycol of different sizes, butylene glycol, and combinations thereof. The amount of

and page 15:

Yet another manner of modifying the erosion kinetics of any layer, is by employing excipients which plasticize the film concomitantly. The excipient or plasticizer often improves the mechanical properties of the device and/or modifies the drug release profile or disintegration time. Suitable excipients or plasticizers modifying the erosion behavior of the layer(s) may include alkyl-glycol such as propylene glycol, polyethyleneglycols, oleate, sebacate, stearate or esters of glycerol, phthalate and others. Other suitable plasticizers include esters such as acetyl citrate, amyl oleate, myristyl acetate, butyl oleate and stearate, dibutyl sebacate, phthalate esters such as diethyl, dibutyl, and diethoxy ethyl phthalate and the like, fatty acids such as oleic and stearic acid, fatty alcohols such as cetyl, myristyl, and stearyl alcohol. Moreover, in some instances, a polymer, a pharmaceutical, or solvent residual may act as a plasticizer.

of the Specification and repeated above for convenience, show the inherent inconsistency between the claims and the Specification to properly render the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-22, 24 and 34-40 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,765,983 to Takayanagi et al .

Takayanagi et al. teach adhesive medical tapes for oral mucosa comprising a support layer composed of an intestine-soluble polymer and a medicament-containing layer composed of a water-soluble polymer containing at least one kind of a steroid or non-steroid antiphlogistic and analgesic medicament (in current claims 19-22, 24 and 34-42; see Abstract), and further comprising a water-soluble polymer such as polyvinylpyrrolidone, sodium carboxymethyl cellulose and hydroxypropyl cellulose (in current claims 22 and 34-40; see col 2 lines 57-end) wherein the thickness of the medicament containing layer (which is two layers) is more than 20µm and at most 300µm (which is equivalent to 0.02-0.3mm: in claim 20 see col 3 lines 5-18).

Although Takayanagi et al. do not specifically recite the inclusion of hydroxyethyl cellulose and hydroxypropylmethyl cellulose as recited in claim 22, they do recite equivalent water-soluble polymers such as hydroxypropyl cellulose and further one of ordinary skill in the art would have recognized hydroxypropyl cellulose as an equivalent particularly in light of such polymer being grouped as a water-soluble polymer and the teaching in the instant Specification that such are equivalents (see page 6 lines 18-25).

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Accordingly, one of ordinary skill in the art would have appreciated the equivalence of including the bioadhesive polymer polyacrylic acid in light of Takayanagi et al.'s teaching of polyvinyl pyrrolidone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-22, 24 and 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,765,983 to Takayanagi et al. in view of US Patent No. 4,594,240 to Kawata et al.

Takayanagi et al. teach adhesive medical tapes for oral mucosa comprising a support layer composed of an intestine-soluble polymer and a medicament-containing layer composed of a water-soluble polymer containing at least one kind of a steroid or non-steroid antiphlogistic and analgesic medicament (in current claims 19-22, 24 and 34-42; see Abstract), and further comprising a water-soluble polymer such as polyvinylpyrrolidone, sodium carboxymethyl cellulose and hydroxypropyl cellulose (in current claims 22 and 34-40; see col 2 lines 57-end) wherein the thickness of the medicament containing layer (which is two layers) is more than 20 μ m and at most 300 μ m (which is equivalent to 0.02-0.3mm: in claim 20 see col 3 lines 5-18).

Although Takayanagi et al. do not specifically recite the inclusion of hydroxyethyl cellulose and hydroxypropylmethyl cellulose as recited in claim 22, they do recite equivalent water-soluble polymers such as hydroxypropyl cellulose and further one of ordinary skill in the art would have recognized hydroxypropyl cellulose as an equivalent particularly in light of such polymer being grouped as a water-soluble polymer and the teaching in the instant Specification that such are equivalents (see page 6 lines 18-25). Accordingly, one of ordinary skill in the art would have appreciated the equivalence of including the bioadhesive polymer polyacrylic acid in light of Takayanagi et al.'s teaching of polyvinyl pyrrolidone.

Kawata et al. teach the use of hydroxyethyl cellulose and polyacrylic acid (in current claims 19, 22, 34 and 38 in particular; see col 2 lines 41-50) in the flexible pharmaceutical containing sheet (see col 1 lines 4-10).

Although neither references specifically teaches the use of the adhesive for a wound or burn site, one of ordinary skill in the art would have found it obvious to use an anti-inflammatory analgesic agent on a site which requires same.

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Takayanagi et al. and Kawata et al. because Takayanagi et al. cite Kawata et al. and further since both are directed to pharmaceutical carrying sheet shaped muco-adhesives. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Response to Arguments

Applicant's arguments filed 18 October 2004 have been fully considered but they are not persuasive. Takayanagi et al. teach that the hydroxyethyl cellulose equivalent, such as hydroxypropyl cellulose, can be in the medicament containing layer (see col 2 lines 60 –end) and that the medicament layer can be both the adhesive layer or the backing layer (see Fig 1 and corresponding text in col 5 lines 64-end).

With regard to the Ventouri reference, Applicant's arguments filed 18 October 2004 have been fully considered but they are persuasive. That the Ventouri reference is no longer deemed necessary the rejection is maintained to the extent that the Takayanagi et al. references teaches all the limitations of claims 19-22, 24 and 34-40.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-22, 24 and 34-42 are rejected on the ground of nonstatutory double patenting over claims 1-27 of U. S. Patent No. 6,159,498 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A biodegradable, water-soluble pharmaceutical carrier device comprising a layered flexible film having a first water-soluble adhesive layer to be placed in contact with the mucosal surface and a second, water-soluble non-adhesive backing layer, and a pharmaceutical or combination of pharmaceuticals incorporated with said first or second layer, wherein said first water-soluble adhesive layer comprises

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hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; and said second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose.

Although the instant application does not recite each of the specific pharmaceutical agents of the reference patent, one of ordinary skill in the art would have considered a protease inhibitor as an obvious antiviral for example or penicillin an obvious antibiotic. And, although the reference patent claims a composition and the instant application claims a method, the composition claimed in the reference patent will be used in the instant method claims.

Claims 19-22, 24 and 34-42 are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 5,800,832 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A bioerodable, water-soluble pharmaceutical carrier device comprising a layered film having a first water-soluble adhesive layer to be placed in contact with the mucosal surface and a second, water-soluble non-adhesive backing layer, and a pharmaceutical or combination of pharmaceuticals incorporated within said first or second layer wherein said first water-soluble adhesive layer comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; said second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose; and said pharmaceutical or combination of pharmaceuticals comprises dyclonine HCl.

Although the instant application does not recite dyclonine HCl in the claims specifically, it is an analgesic which is listed on page 17 of the instant specification and therefore included within the scope of the instant claims.

Claims 19-22, 24 and 34-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 15-18 and 33-34 of copending Application No. 09/069703. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '703 application claims a water-erodible pharmaceutical carrier device comprising a layered flexible film having a first water-erodible adhesive layer to be placed in contact with a mucosal surface, a second, water-erodible non-adhesive backing layer, and a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodible adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodible non-adhesive backing layer comprises hydroxyethyl cellulose and further wherein the total thicknesses of the adhesives overlap.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6 December 2005
MG


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